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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/701,041	11/04/2003	Benjamin Oshlack	200.1133CON2	6154

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DAVIDSON, DAVIDSON & KAPPEL, LLC
14th Floor
485 Seventh Avenue
New York, NY 10018

EXAMINER	
ALSTRUM ACEVEDO, JAMES HENRY	
ART UNIT	**PAPER NUMBER**
1616	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/701,041	OSHLACK ET AL.	
	Examiner	Art Unit	
	James H. Alstrum-Acevedo	1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *18 May 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *62-74* is/are pending in the application.

4a) Of the above claim(s) *68* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *62-67 and 69-74* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *See Continuation Sheet*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Continuation of Attachment(s) 3). Information Disclosure Statement(s) (PTO/SB/08), Paper No(s)/Mail Date :7/13/07; 5/18/07; 6/13/06; 9/9/04; 11/4/03.

DETAILED ACTION

Claims 62-74 are pending. Applicants cancelled claims 1-61 in a preliminary amendment. Applicants have amended claim 68. Claim 68 is withdrawn from consideration as being drawn to a non-elected species.. **Claims 62-67 and 69-74 are under consideration in the instant office action.** Receipt and consideration of Applicants' IDS's (submitted 7/31/07; 5/18/07; 6/13/06; 9/9/04; and 11/4/03) and remarks/arguments submitted on May 18, 2007 are acknowledged.

Election/Restrictions

Claim 68 is withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected species, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on May 18, 2007.

The requirement is still deemed proper and is therefore made FINAL.

Specification

The lengthy specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

The use of the trademarks TALWIN® ([0011]), TEMGESIC® ([0011]), EUDRAGIT® ([0116], [0145], [0147], [0151], [0214], [0305], [0440], [0441]), AQUACOAT® ([0139], [0156], [0157]), SURELEASE® ([0140] and [0156]), OPADRY® ([0158]), and AVICEL PH 101®

([0184]) have been noted in this application. Trademarks should be capitalized wherever it appears and be accompanied by the generic terminology.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner, which might adversely affect their validity as trademarks.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:
The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

Claims 66-68 and 70 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 66 and 70 are indefinite because said claims recite derivatives of fentanyl, however, the instant specification does not define a "fentanyl derivative." The 10th edition of the Merriam-Webster's Collegiate Dictionary (Merriam-Webster Incorporated: Springfield, Massachusetts, 1993, pp 311) defines "derivative" as, "a chemical substance related structurally to another substance and theoretically derivable from it." For example, carbon dioxide could theoretically be derived from the combustion of fentanyl. Therefore, the definition of derivative in the Merriam-Webster Collegiate Dictionary does not shed light on what Applicants' intended for the meaning of a fentanyl derivative.

The remaining claims are rejected as depending from a rejected claim.

Claim Rejections - 35 USC § 102

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 62-63, 65-67, 71, and 73-74 are rejected under 35 U.S.C. 102(e) as being anticipated by Mehta (US 2004/0202717).

Applicant Claims

Applicants claim (1) a composition comprising (i) an inert core, (ii) a fist layer, and (iii) a second layer, the first layer being located between the core and the second layer, and the second layer consisting essentially of an opioid antagonist (e.g. naltrexone) and the second layer a hydrophobic material and (2) an oral dosage form comprising an opioid agonist (e.g. oxycodone) and the composition of claim 62 (i.e. composition (1), as described above).

Mehta discloses abuse-resistant oral dosage forms and methods of use thereof, wherein in one embodiment an opioid antagonist layer is coated onto a biologically inert pellet and a non-releasing membrane coated onto the opioid antagonist layer (title; abstract; [0021]; [0027]; [0048]-[0058]; claims 13, 15-17, 35, and 37-39). Examples of suitable opioid antagonists include, **naltrexone, naloxone, and naltrexone, preferably naltrexone** [0022]. Examples of suitable non-releasing membranes include water-retardant polymers (i.e. hydrophobic materials) such as **alkyl cellulose, acrylic acid polymer, poly(meth)acrylate polymer (e.g. EUDRAGIT NE 30D®)** [0028]. In one embodiment, the non-releasing membrane is coated with an opioid agonist layer [0032]. **Suitable opioid agonists include oxycodone, hydrocodone, morphine, hydromorphone, codeine, and mixtures thereof** [0032]. Mehta's dosage form is an effective

way of preventing abuse of an oral dosage form of an opioid agonist, because the physical alteration of Mehta's oral dosage form will effectively release the opioid antagonist, thus neutralizing the opioid agonist and the intended analgesic and/or euphoric effect [0033].

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Applicant Claims
2. Determining the scope and contents of the prior art.
3. Ascertaining the differences between the prior art and the claims at issue, and resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later

invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 64, 69-70, and 72 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mehta (US 2004/0202717).

Applicant Claims

Applicants' claims have been described above in the instant office action.

Determination of the Scope and Content of the Prior Art (MPEP §2141.01)

The disclosures of Mehta have been set forth above in the instant office action.

Ascertainment of the Difference Between Scope the Prior Art and the Claims (MPEP §2141.012)

Mehta lacks the express teaching of the amount of hydrophobic material by weight in the composition/oral dosage form. This deficiency is obviated by the teachings of Mehta and the routine practices in the art.

Finding of Prima Facie Obviousness Rational and Motivation (MPEP §2142-2143)

It would have been prima facie obvious to a person of ordinary skill in the art at the time of the instant invention that the amount of hydrophobic material utilized in the Mehta's disclosed compositions/oral dosage forms is a result effective parameter, because said hydrophobic material clearly functions to prevent the release of the opioid antagonist when the Mehta's

compositions/dosage form is taken in the prescribed manner. The amount of a specific ingredient in a composition is clearly a result effective parameter that a person of ordinary skill in the art would routinely optimize. Optimization of parameters is a routine practice that would be obvious for a person of ordinary skill in the art to employ. It would have been customary for an artisan of ordinary skill to determine the optimal amount of each ingredient needed to achieve the desired results. Thus, absent some demonstration of unexpected results from the claimed parameters, the optimization of ingredient amounts would have been obvious at the time of applicant's invention. Applicants' data as depicted in Figures 1-3 in the specification is noted. Applicants' data does not demonstrate unexpected results, because it merely pictorially demonstrates a property textually articulated by Mehta, namely that the opioid antagonist is not readily released from the invented dosage forms unless the dosage form is physically altered, such as by grinding or crushing. Therefore, the claimed invention, as a whole, would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, because the combined teachings of the prior art is fairly suggestive of the claimed invention.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 63 and 71-72 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 48, 51, and 56 of copending Application No. 10/389,238 (copending '238). Although the conflicting claims are not identical, they are not patentably distinct from each other because the cited claims of both applications are substantially overlapping in scope and mutually obvious. Independent claim 62 of the instant application has been described above in the instant office action. Independent claim 48 of copending '238 claims a pharmaceutical composition comprising (i) an inert core, (ii) a 1st layer, and (iii) a 2nd layer, the 1st layer being between the core and the 2nd layer and comprising a mixture of naltrexone hydrochloride and a stabilizer, and the second layer comprising a hydrophobic material. Independent claim 51 of copending '238 claims a pharmaceutical composition comprising a 1st component comprising about 10 mg of oxycodone hydrochloride and a 2nd component comprising less than about 5.0 mg naltrexone hydrochloride and a stabilizer, wherein said 2nd component comprises a plurality of substrates comprising a mixture of naltrexone hydrochloride and stabilizer. Therefore, a person of ordinary skill in the art at the time of the instant invention would have found claims 63 and 71-72 of the instant application *prima facie* obvious over claims 48, 51, and 56 of copending Application No. 10/389,238 (copending '238).

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 62-63 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 41 of copending Application No. 10/401,111 (copending '111). Although the conflicting claims are not identical, they are not patentably distinct from each other because the cited claims of both applications are substantially overlapping in scope and mutually obvious. Independent claim 62 of the instant application has been described above in the instant office action. Independent claim 41 of copending '111 an oral dosage form comprising (i) an inert core, (ii) a 1st layer, and (iii) a 2nd layer, the 1st layer being between the core and the 2nd layer and comprising a mixture of naltrexone hydrochloride and a stabilizer, and the second layer comprising a mixture of gelatin and a hydrophobic material. Therefore, a person of ordinary skill in the art at the time of the instant invention would have found claims 62-63 of the instant application *prima facie* obvious over claim 41 of copending Application No. 10/401,111 (copending '111).

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 62-64 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 2-3 and 15-17 of copending Application No. 10/524,334 (copending '334). Although the conflicting claims are not identical, they are not patentably distinct from each other because the cited claims of both

applications are substantially overlapping in scope and mutually obvious. Independent claim 62 of the instant application has been described above in the instant office action. Independent claim 1 of copending '334 an oral dosage form comprising (i) a substrate comprising an opioid antagonist (e.g. an inert core, such as is recited in claims 2-3 of copending '334) (ii) a diffusion barrier coating comprising an anionic polymer over said substrate layer, and (iii) a coating comprising a hydrophobic material coated over said diffusion barrier coating. Dependent claims 15-16 of copending '334 further specify the nature of the coating material as being a hydrophobic material that provides sequestration of the opioid antagonist. Dependent claim 17 of copending '334 claims the pharmaceutical formulation of claim 1, wherein the opioid antagonist is selected from the group consisting of naltrexone, naloxone, and pharmaceutically acceptable salts thereof. Therefore, a person of ordinary skill in the art at the time of the instant invention would have found claims 62-64 of the instant application *prima facie* obvious over claims 2-3 and 15-17 of copending Application No. 10/514.334 (copending '334).

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 62 and 64 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 62-63 and 65 of copending Application No. 10/700,861 (copending '861). Although the conflicting claims are not identical, they are not patentably distinct from each other because the cited claims of both applications are substantially overlapping in scope and mutually obvious. Independent claim 62 of the instant application has been described above in the instant office action. Independent

claim 41 of copending '861 an oral dosage form comprising (i) an inert core, (ii) a 1st layer, and (iii) a 2nd layer, the 1st layer being between the core and the 2nd layer and comprising an opioid antagonist, the 2nd layer comprising a 1st hydrophobic material, and the 3rd layer comprising a 2nd hydrophobic material. Therefore, a person of ordinary skill in the art at the time of the instant invention would have found claims 62 and 64 of the instant application *prima facie* obvious over claims 62-63 and 65 of copending Application No. 10/700,861 (copending '861).

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Conclusion

Claims 62-67 and 69-74 are rejected. The specification is objected. No claims under consideration in the instant office action are allowed.

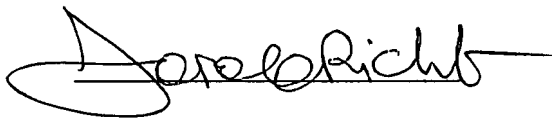
Any inquiry concerning this communication or earlier communications from the examiner should be directed to James H. Alstrum-Acevedo whose telephone number is (571) 272-5548. The examiner can normally be reached on M-F, 9:00-6:30, with every other Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann Richter can be reached on (571) 272-0646. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications

may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

James H. Alstrum-Acevedo
Patent Examiner
Technology Center 1600



Johann R. Richter
Supervisory Patent Examiner
Technology Center 1600